Amendment No. 1 to HB0948

Terry
Signature of Sponsor

AMEND Senate Bill No. 1281 House Bill No. 948*

by deleting all language after the enacting clause and substituting:

SECTION 1. Tennessee Code Annotated, Title 68, Chapter 11, Part 16, is amended by deleting the part and substituting:

68-11-1601. Short title.

This part is known and may be cited as the "Tennessee Health Services and Planning Act of 2021."

68-11-1602. Part definitions.

As used in this part:

(1) "Agency" and "health services and development agency" mean the agency created by this part to develop the criteria and standards to guide the agency when issuing certificates of need; to conduct studies related to health care, including needs assessments; and to administer the certificate of need program and related activities;

(2) "Certificate of need" means a permit granted by the health services and development agency to a person for those services specified as requiring a certificate of need under § 68-11-1607 at a designated location;

(3) "Conflict of interest" means a matter before the agency in which the member or employee of the agency has a direct interest or indirect interest that is in conflict or gives the appearance of conflict with the discharge of the member's or employee's duties;

(4) "Department" means the department of health;

(5) "Direct interest" means a pecuniary interest in the persons involved in a matter before the agency, and applies to the agency member or employee, the agency member's or employee's relatives, or an individual with whom or business in which the member or employee has a pecuniary interest. As used in this subdivision (5), "relative" means a spouse, parent, child, stepparent, stepchild, grandparent, grandchild, brother, sister, half-brother, half-sister, aunt, uncle, niece, or nephew by blood, marriage, or adoption;

(6) "Ex parte communications" means communications in violation of § 4-5-304 or § 68-11-1607(d);

(7) "Facility" means real property owned, leased, or used by a healthcare institution for any purpose, other than as an investment;

(8) "Health service" means clinically related services, such as diagnostic, treatment, or rehabilitative services, and includes those services specified as requiring a certificate of need under § 68-11-1607;

(9) "Healthcare institution":

(A) Means an agency, institution, facility, or place, whether publicly or privately owned or operated, that provides health services and that is one (1) of the following:

(i) A nursing home;

(ii) A hospital;

(iii) An ambulatory surgical treatment center;

(iv) An intellectual disability institutional habilitation facility;

(v) A home care organization, or a category of service provided by a home care organization for which authorization is required under part 2 of this chapter;

(vi) An outpatient diagnostic center;

(vii) A rehabilitation facility;

(viii) A residential hospice; or

(ix) A nonresidential substitution-based treatment center for opiate addiction; and

(B) Does not include:

(i) A ground ambulance;

(ii) A home for the aged;

(iii) A premises occupied exclusively as the professional practice office of a:

(*a*) Physician licensed pursuant to title 63, chapter 6, part 2 or title 63, chapter 9; or

(*b*) Dentist licensed by this state and controlled by the physician or dentist;

(iv) An administrative office building of a public agency related to healthcare institutions;

(v) A Christian Science sanatorium operated, or listed and certified, by the First Church of Christ Scientist, Boston, Massachusetts;

(vi) A mental health residential treatment facility; or

(vii) A mental health hospital;

(10) "Home care organization" means an entity licensed as such by the department that is staffed and organized to provide "home health services" or "hospice services," as defined by § 68-11-201, to patients in either the patient's regular or temporary place of residence;

(11) "Indirect interest" means a personal interest in the persons involved in a matter before the agency that is in conflict with the discharge of the agency member's or employee's duties;

(12) "Letter of intent" means the form prescribed by the agency that requires a brief project description, location, estimated project cost, owner of the project, and description of services to be performed;

(13) "Licensed beds" means the number of beds licensed by the agency having licensing jurisdiction over the facility in which the beds are located;

(14) "Needs assessment" means an annual report that measures access to health care in this state, particularly as to emergency and primary care; identifies access gaps; and serves to inform the criteria and standards for the issuance of certificates of need;

(15) "Nonresidential substitution-based treatment center for opiate addiction" includes, but is not limited to, stand-alone clinics offering methadone, products containing buprenorphine such as Subutex and Suboxone, or products containing any other formulation designed to treat opiate addiction by preventing symptoms of withdrawal;

(16) "Nursing home" has the same meaning as defined in § 68-11-201;

(17) "Nursing home bed" means:

(A) A licensed bed within a nursing home, regardless of whether the bed is certified for medicare or medicaid services; and

(B) A bed at a healthcare institution used as a swing bed under 42 C.F.R. § 485.645;

(18) "Patient" includes, but is not limited to, a person who has an acute or chronic physical or mental illness or injury; who is convalescent, infirm, or has an intellectual or physical disability; or who is in need of obstetrical, surgical, medical, nursing, psychiatric, or supervisory care;

(19) "Pediatric patient" means a patient who is fourteen (14) years of age or younger;

(20) "Person":

(A) Means an individual, a trust or an estate, a firm, a partnership, an association, a stockholder, a joint venture, a corporation or other form of business organization, the state of Tennessee and its political subdivisions or parts of political subdivisions, and any combination of persons specified in this subdivision (20), public or private; and

(B) Does not include the United States or an agency or instrumentality of the United States, except in the case of voluntary submission to the rules established pursuant to this part;

(21) "Planning division" and "state health planning division" mean the state health planning division of the department, which is created by this part to develop the state health plan and conduct other related studies;

(22) "Rehabilitation facility" means an inpatient or residential facility that is operated for the primary purpose of assisting in the rehabilitation of physically disabled persons through an integrated program of medical and other services that is provided under professional supervision;

(23) "Review cycle" means the timeframe set for the review and initial decision on applications for certificate of need applications that have been deemed complete, with the fifteenth day of the month being the first day of the review cycle; and

(24) "State health plan" means the plan that is developed by the state health planning division pursuant to this part.

68-11-1603. Policy.

It is declared to be the public policy of this state that the establishment and modification of healthcare institutions, facilities, and services must be accomplished in a manner that promotes access to necessary, high quality, and cost-effective services for the health care of the people of this state. To this end, this section applies equitably to

all healthcare entities, regardless of ownership or type, except those owned and operated by the United States government.

68-11-1604. Health services and development agency — Creation — Composition — Appointments — Terms — Compensation — Officers — Meetings — Conflict of interest.

(a) There is created a health services and development agency that has jurisdiction and powers relating to the certificate of need program; the development of the criteria and standards to guide the agency when issuing certificates of need; conducting of studies related to health care, which must include a needs assessment; and related reporting of healthcare institutions subject to this chapter.

(b)

(1) The agency consists of eleven (11) members, including:

(A) The comptroller of the treasury, or an employee of the office of the comptroller of the treasury designated by the comptroller;

(B) The state director of TennCare, or its successor, or an employee of the division of TennCare, or its successor, designated by the director;

(C) The commissioner of commerce and insurance, or an employee of the department of commerce and insurance designated by the commissioner;

(D) One (1) consumer member appointed by the speaker of the senate;

(E) One (1) consumer member appointed by the speaker of the house of representatives; and

(F) Six (6) members appointed by the governor, to include:

(i) One (1) person who has recent experience as an executive officer of a hospital or hospital system who may be

appointed from lists of qualified persons submitted by interested hospital groups, including, but not limited to, the Tennessee Hospital Association;

(ii) One (1) representative of the nursing home industry who may be appointed from lists of qualified persons submitted by interested healthcare groups, including, but not limited to, the Tennessee Health Care Association;

(iii) One (1) duly licensed physician who may be appointed from lists of qualified persons submitted by interested medical groups, including, but not limited to, the Tennessee Medical Association;

(iv) One (1) representative of the home care industry who may be appointed from lists of qualified persons submitted by interested home care groups, including, but not limited to, the Tennessee Association for Home Care. The initial term for the home care industry representative is two (2) years. Upon the expiration of that term, the home care industry representative is appointed for a three-year term pursuant to subsection (c);

(v) One (1) consumer member; and

(vi) One (1) representative of the ambulatory surgical treatment center industry.

(2) The governor shall consult with interested groups, including, but not limited to, the organizations listed in subdivision (b)(1) to determine qualified persons to fill positions with the agency.

(3) In making appointments to the health services and development agency, the governor and the speakers shall strive to ensure that racial

minorities, females, persons sixty (60) years of age and older, and the three (3) grand divisions are represented.

(4) The consumer members must be persons who are knowledgeable of health needs and services and who are further knowledgeable by training or experience in healthcare facility design or construction, financing of healthcare services or construction, reimbursement of healthcare services, or general healthcare economics. The consumer members shall not be a direct provider of healthcare goods or services.

(c)

(1) A member of the agency shall not serve beyond the expiration of the member's term, whether or not a successor has been appointed by the governor or the speakers of the senate and the house of representatives.

(2) Except for the comptroller of the treasury, the commissioner of commerce and insurance, and the director of TennCare, or their respective designees, agency members are appointed for three-year terms, and a member shall not serve more than two (2) consecutive three-year terms.

(3) If a member is absent from three (3) consecutive, regularly scheduled public meetings of the agency, then the individual's membership is automatically terminated, and the position is considered as vacant.

(d)

(1) Each member of the agency shall receive fifty dollars ($50.00) per diem when actually engaged in the discharge of the member's official duties, and in addition, shall be reimbursed for all travel and other necessary expenses. However, agency members who are state employees shall not receive per diem, but must be reimbursed for all travel and other necessary expenses.

(2) Expenditures must be claimed and paid in accordance with the comprehensive travel regulations as promulgated by the department of finance and administration, and approved by the attorney general and reporter.

(e)

(1) At the first meeting in each fiscal year, the agency shall elect officers. The chair of the agency must be a consumer member to serve a term of two (2) years. A member of the agency may serve as vice chair, which is a term of one (1) year. A member shall not serve two (2) consecutive terms as vice chair.

(2) Meetings of the agency must be held as frequently as its duties may require.

(3) Six (6) members constitute a quorum, but a vacancy on the agency does not impair its power to act.

(4) An action of the agency is not effective unless the action is concurred in by a majority of agency members present and voting.

(5) In the event of a tie vote, the action is considered disapproved.

(6) The agency shall record by name the votes taken on all actions of the agency.

(7)

(A) All agency members shall annually review and sign a statement acknowledging the statute, rules, and policies concerning conflicts of interest.

(B)

(i) A member, upon determining that a matter scheduled for consideration by the agency results in a conflict with a direct interest, shall immediately notify the executive director and is recused from any deliberation of the matter, from making any recommendation, from testifying concerning the matter, or from

voting on the matter. The member shall join the public during the proceedings.

(ii) A member with an indirect interest shall publicly acknowledge such interest.

(iii) All members shall make every reasonable effort to avoid even the appearance of a conflict of interest. If a member is uncertain whether the relationship justifies recusal, then the member shall follow the determination by the legal counsel for the agency.

(iv) A determination by the agency or a court that a member of the agency with a direct interest failed to provide notice and be recused from deliberations of the matter, from making any recommendation, from testifying concerning the matter, or from voting on the matter, results in the member's automatic termination from the agency and the position is considered vacant. The member is not eligible for appointment to any agency, board, or commission of this state for a period of two (2) years.

(v) The executive director, upon determining that a conflict exists for the executive director or a member of the staff, shall notify the chair of the agency and take such action as the chair prescribes and pursuant to this part.

68-11-1605. Powers and duties of agency.

In addition to the powers granted elsewhere in this part, the agency has the duty and responsibility to:

(1) Develop criteria and standards to guide the agency when issuing certificates of need that are:

(A) Based, in whole or in part, upon input the agency received during development of the criteria and standards from the division of TennCare, or its successor; the departments of health, mental health and substance abuse services, and intellectual and developmental disabilities; the health and welfare committee of the senate; and the health committee of the house of representatives;

(B) Evaluated and updated not less than once every five (5) years; and

(C) Developed by rule in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5;

(2) Receive and consider applications for certificates of need, to review recommendations on certificates of need, and to grant or deny certificates of need on the basis of the merits of the applications within the context of the local, regional, and state health needs, including, but not limited to, the criteria and standards developed in accordance with this part;

(3) Conduct studies related to health care, including a needs assessment that must be updated at least annually;

(4) Promulgate rules and policies deemed necessary by the agency for the fulfillment of its duties and responsibilities under this part, including a procedure for the issuance of a certificate of need upon an emergency application if an unforeseen event necessitates the issuance of a certificate of need to protect the public health, safety, and welfare, and if the public health, safety, and welfare would be unavoidably jeopardized by compliance with the procedures established under this part;

(5) Contract when necessary for the development of criteria and standards to guide the agency when issuing certificates of need and for the implementation of the certificate of need program described in this part;

(6) Weigh and consider access to quality health care and the healthcare needs of consumers, particularly those in underserved communities; those who are uninsured or underinsured; women and racial and ethnic minorities; TennCare or medicaid recipients; and low-income groups whenever the agency performs its duties or responsibilities assigned by law; and

(7) Issue exemptions from the voiding of a certificate of need and an activity authorized by the certificate of need pursuant to § 68-11-1609(i), if the actions the certificate of need authorizes are not performed for a continuous period of one (1) year after the date the certificate of need is implemented.

68-11-1606. Executive director of agency — Appointment — Salary — Duties — Delegation of authority — Review.

(a) The agency shall appoint an executive director qualified by education and experience. The executive director must demonstrate knowledge and experience in the areas of public administration and health policy development.

(b) The agency shall fix the salary of the executive director, who serves at the pleasure of the agency. The executive director is the chief administrative officer of the agency and the appointing authority, exercising general supervision over all persons employed by the agency.

(c) The executive director has the following duties:

(1) Administering the development of criteria and standards to guide the agency when issuing certificates of need;

(2) Administering the certificate of need program;

(3) Conducting studies related to health care;

(4) Representing the agency before the general assembly;

(5) Overseeing the issuance of responses to requests for determination regarding the applicability of this part;

(6) Issuing exemptions from the requirement that a certificate of need be obtained for the relocation of existing or certified facilities providing healthcare services and healthcare institutions under § 68-11-1607(a)(4);

(7) Keeping a written record of proceedings and transactions of the agency, which must be open to public inspection during regular office hours;

(8) Preparing the agenda, including consent and emergency calendars, and notice to the general public of all meetings and public hearings of the agency;

(9) Employing personnel, within the agency's budget, to assist in carrying out this part;

(10) Carrying out policies and rules that are promulgated by the agency and supervising the expenditure of funds;

(11) Submitting an annual report, no later than January 15 of each year, to the chairs of the health and welfare committee of the senate and the health committee of the house of representatives that includes, but is not limited to, a comparison of the actual payer mix and uncompensated care provided by certificate of need holders with the projections the holders submitted in the holder's certificate of need application; and

(12) Submitting to the chairs of the health and welfare committee of the senate and health committee of the house of representatives no later than January 1, 2023, a plan:

(A) Developed by the executive director;

(B) To consolidate into a health facilities commission the powers and duties of the agency with those of the board for licensing health care facilities established under part 2 of this chapter; and

(C) For which agencies of this state shall provide assistance to the executive director following a request by the executive director.

(d) In addition to the duties provided in subsection (c), the agency has the authority to delegate, and it is the intent of the general assembly that the agency exercise the authority to delegate the following responsibilities and duties to the executive director:

(1) Granting deferral of applications for certificates of need in accordance with § 68-11-1609; and

(2) Granting approval or denial of modifications, changes of conditions or ownership, and extensions of certificates of need in accordance with this part.

(e) A delegation of authority pursuant to subsection (d) continues until specifically revoked by the agency as a result of a determination that revocation is necessary to ensure the proper and orderly operation of the agency.

(f) The executive director shall, within two (2) business days, notify the agency of an action taken pursuant to a delegation of authority under subsection (d).

(g)

(1) The agency shall review an action by the executive director, if:

(A) The executive director receives a written request for agency review; or

(B) An agency member requests agency review.

(2)

(A) If a request for agency review pursuant to subdivision (g)(1) is received within fifteen (15) days of the date the executive director provides notice of the action pursuant to subsection (f), then the action does not become final until the agency has rendered its final decision.

(B) If a request for agency review is not received pursuant to subdivision (g)(1), then the executive director's action becomes final as if the action was taken by the agency.

(h)

(1) An agency review of an action taken by the executive director must be conducted at the next regularly scheduled agency meeting that is scheduled for a date no less than two (2) weeks after the date the request for review is received pursuant to subsection (g).

(2) Agency review of an action by the executive director is de novo.

(3) The agency shall use the then-current edition of Robert's Rules of Order as the rules of parliamentary procedure applicable to an agency review of an action taken by the executive director.

68-11-1607. Certificate of need — Applications — Exemptions — Registration of equipment — Critical access hospital designation.

(a) A person shall not perform the following actions in this state, except after applying for and receiving a certificate of need for the action:

(1) The construction, development, or other establishment of any type of healthcare institution as described in this part;

(2) In the case of a healthcare institution, a change in the bed complement, regardless of cost, that:

(A) Increases by one (1) or more the number of nursing home beds;

(B) Redistributes beds from any category to acute, rehabilitation, or long-term care, if at the time of redistribution the healthcare institution does not have beds licensed for the category to which the beds will be redistributed; or

(C) Relocates beds to another facility or site;

(3) Initiation of the following healthcare services:

(A) Burn unit;

(B) Neonatal intensive care unit;

(C) Open heart surgery;

(D) Organ transplantation;

(E) Cardiac catheterization;

(F) Linear accelerator;

(G) Home health;

(H) Hospice; or

(I) Opiate addiction treatment provided through a nonresidential substitution-based treatment center for opiate addiction;

(4)

(A) Except as provided in subdivision (a)(4)(B), a change in the location of existing or certified facilities providing healthcare services and healthcare institutions. However, the executive director may issue an exemption for the relocation of existing healthcare institutions and approved services if the executive director determines that:

(i)

(a) At least seventy-five percent (75%) of patients to be served are reasonably expected to reside in the same zip codes as the existing patient population; and

(b) The relocation will not reduce access to consumers, particularly those in underserved communities; those who are uninsured or underinsured; women and racial and ethnic minorities; TennCare or medicaid recipients; and low-income groups;

(ii) The executive director must notify the agency of an exemption granted pursuant to subdivision (a)(4)(A)(i) within two (2) business days of the date the executive director grants the exemption;

(iii) An exemption granted by the executive director pursuant to subdivision (a)(4)(A)(i) is subject to agency review in the same manner as described in § 68-11-1606(g) and (h);

(B) The relocation of the principal office of a home health agency or hospice within its licensed service area does not require a certificate of need;

(5) Except as otherwise provided in subdivision (m)(2) and subsection (u), the following actions in a county with a population of one hundred seventy-five thousand (175,000) or less, according to the 2010 federal census or any subsequent federal census:

(A) Initiation of magnetic resonance imaging services; or

(B) Increasing the number of magnetic resonance imaging machines, except for replacing or decommissioning an existing machine;

(6) Establishing a satellite emergency department facility or a satellite inpatient facility by a hospital at a location other than the hospital's main campus; and

(7) Except as otherwise provided in subsection (u), the initiation of positron emission tomography in a county with a population of one hundred seventy-five thousand (175,000) or less, according to the 2010 federal census or any subsequent federal census.

(b) An agency of this state, or of a county or municipal government, shall not approve a grant of funds for, or issue a license to, a healthcare institution for a portion or activity of the healthcare institution that is established, modified, relocated, changed, or resumed, or that constitutes a covered healthcare service, in violation of this part. If an agency of this state, or of a county or municipal government, approves a grant of funds for, or issues a license to, a person or institution for which a certificate of need was required but was not granted, then the license is void and the person or institution shall

refund the funds to the state within ninety (90) days. The health services and development agency has the authority to impose civil penalties and petition a circuit or chancery court having jurisdiction to enjoin a person who is in violation of this part.

(c)

(1) For each application, a letter of intent must be filed between the first day of the month and the fifteenth day of the month prior to the application's submission. At the time of filing, the applicant shall cause the letter of intent to be published in a newspaper of general circulation in the proposed service area of the project. The published letter of intent must contain a statement that any:

(A) Healthcare institution wishing to oppose the application must file written notice with the agency no later than fifteen (15) days before the agency meeting at which the application is originally scheduled; and

(B) Other person wishing to oppose the application may file a written objection with the agency at or prior to the consideration of the application by the agency, or may appear in person to express opposition.

(2) Persons desiring to file a certificate of need application seeking a simultaneous review regarding a similar project for which a letter of intent has been filed shall file with the agency a letter of intent between the sixteenth day of the month and the last day of the month of publication of the first filed letter of intent. A copy of a letter of intent filed after the first letter of intent must be mailed or delivered to the first filed applicant and must be published in a newspaper of general circulation in the proposed service area of the first filed applicant. The health services and development agency shall consider and decide the applications simultaneously. However, the agency may refuse to consider the applications simultaneously if it finds that the applications do not meet the requirements of "simultaneous review" under the rules of the agency.

(3) Applications for a certificate of need, including simultaneous review applications, must be filed by the first business day of the month following the date of publication of the letter of intent.

(4) If there are two (2) or more applications to be reviewed simultaneously in accordance with this part and the rules of the agency, and one (1) or more of those applications is not deemed complete by the deadline to be considered at the next agency meeting, then the other applications that are deemed complete by the deadline must be considered at the next agency meeting. The application or applications that are not deemed complete by the deadline to be considered at the next agency meeting will not be considered with the applications deemed complete by the deadline to be considered at the next agency meeting.

(5) Review cycles begin on the fifteenth day of each month. Review cycles are thirty (30) days. The first meeting at which an application can be considered by the agency is the meeting following the application's review cycle. If an application is not deemed complete within sixty (60) days after initial written notification is given to the applicant by agency staff that the application is deemed incomplete, then the application is void. If the applicant decides to resubmit the application, then the applicant shall comply with all procedures as set out by this part and pay a new filing fee when submitting the application. Prior to deeming an application complete, the executive director shall ensure independent review and verification of information submitted to the agency in applications, presentations, or otherwise. The purpose of the independent review and verification is to ensure that the information is accurate, complete, comprehensive, timely, and relevant to the decision to be made by the agency. The independent review and verification must be applied to, but not necessarily be limited to, applicant-provided information as to the number of available beds

within a region, occupancy rates, the number of individuals on waiting lists, the demographics of a region, the number of procedures, and other critical information submitted or requested concerning an application; and staff examinations of data sources, data input, data processing, and data output, and verification of critical information.

(6) An application filed with the agency must be accompanied by a nonrefundable examination fee fixed by the rules of the agency.

(7) Information provided in the application or information submitted to the agency in support of an application must be true and correct. Substantive amendments to the application, as defined by rule of the agency, are not allowed.

(8) An applicant shall designate a representative as the contact person for the applicant and shall notify the agency, in writing, of the contact person's name, address, and telephone number. The applicant shall immediately notify the agency in writing of any change in the identity or contact information of the contact person. In addition to any other method of service permitted by law, the agency may serve by registered or certified mail any notice or other legal document upon the contact person at the person's last address of record in the files of the agency. Notwithstanding a law to the contrary, service in the manner specified in this subdivision (c)(8) constitutes actual service upon the applicant.

(9)

(A) Within ten (10) days of the filing of an application for a nonresidential substitution-based treatment center for opiate addiction with the agency, the applicant shall send a notice to the county mayor of the county in which the facility is proposed to be located; the state representative and senator representing the house district and the senate district in which the facility is proposed to be located; and the mayor of the municipality, if the facility is proposed to be located within the corporate

boundaries of a municipality, by certified mail, return receipt requested, informing those officials that an application for a nonresidential substitution-based treatment center for opiate addiction has been filed with the agency by the applicant.

(B) If an application involves a healthcare facility in which a county or municipality is the lessor of the facility or real property on which it sits, then within ten (10) days of filing the application, the applicant shall notify the chief executive officer of the county or municipality of the filing, by certified mail, return receipt requested.

(C) An application subject to the notification requirements of this subdivision (c)(9) is not complete if the applicant has not provided proof of compliance with this subdivision (c)(9) to the agency.

(d) Communications with the members of the agency are not permitted once the letter of intent initiating the application process is filed with the agency. Communication between agency members and agency staff is not prohibited. Any communication received by an agency member from a person unrelated to the applicant or party opposing the application must be reported to the executive director, and a written summary of the communication must be made part of the certificate of need file.

(e) For purposes of this part, agency action is the same as administrative action defined in § 3-6-301.

(f)

(1) Notwithstanding this section to the contrary, Tennessee state veterans' homes under title 58, chapter 7, are not required to obtain a certificate of need pursuant to this section.

(2) Notwithstanding this section to the contrary, the beds located in a Tennessee state veterans' home pursuant to title 58, chapter 7, must not be considered by the health services and development agency when granting a

certificate of need to a healthcare institution due to a change in the number of licensed beds, redistributing beds, or relocating beds pursuant to this section.

(g) After a person holding a certificate of need has completed the actions for which the certificate of need was granted, the time to complete activities authorized by the certificate of need expires.

(h) The owners of the following types of equipment shall register the equipment with the health services and development agency: computerized axial tomographers, magnetic resonance imagers, linear accelerators, and positron emission tomography. The registration must be in a manner and on forms prescribed by the agency and must include ownership, location, and the expected useful life of the equipment. Registration must occur within ninety (90) days of acquisition of the equipment. All such equipment must be filed on an annual inventory survey developed by the agency. The survey must include, but not be limited to, the identification of the equipment and utilization data according to source of payment. The survey must be filed no later than thirty (30) days following the end of each state fiscal year. The agency may impose a penalty not to exceed fifty dollars ($50.00) for each day the survey is late.

(i) Notwithstanding this section to the contrary, an entity, or its successor, that was formerly licensed as a hospital, and that has received from the commissioner of health a written determination that it will be eligible for designation as a critical access hospital under the medicare rural hospital flexibility program, is not required to obtain a certificate of need to establish a hospital qualifying for that designation, if it meets the requirements of this subsection (i). In order to qualify for the exemption set forth in this subsection (i), the entity proposing to establish a critical access hospital shall publish notice of its intent to do so in a newspaper of general circulation in the county where the hospital will be located and in contiguous counties. The notice must be published at least twice within a fifteen-day period. The written determination from the department of health and proof of publication required by this subsection (i) must be filed with the

agency within ten (10) days after the last date of publication. If no healthcare institution within the same county or contiguous counties files a written objection to the proposal with the agency within thirty (30) days of the last publication date, then the exemption set forth in this subsection (i) applies. However, this exemption applies only to the establishment of a hospital that qualifies as a critical access hospital under the medicare rural flexibility program and not to any other activity or service. If a written objection by a healthcare institution within the same county or contiguous counties is filed with the agency within thirty (30) days from the last date of publication, then the exemption set forth in this subsection (i) does not apply.

(j)

(1) Notwithstanding subdivision (a)(2)(A) or (a)(4), a nursing home may increase its total number of licensed beds by the lesser of ten (10) beds or ten percent (10%) of its licensed capacity no more frequently than one (1) time every three (3) years without obtaining a certificate of need. The nursing home shall provide written notice of the increase in beds to the agency on forms provided by the agency prior to the request for licensing by the board for licensing health care facilities.

(2) For new nursing homes, the ten-bed or ten-percent increase cannot be requested until one (1) year after the date all of the new beds were initially licensed.

(3) When determining projected county nursing home bed need for certificate of need applications, all notices filed with the agency pursuant to subdivision (j)(1), with written confirmation from the board for licensing health care facilities that a request and application for license has been received and a review has been scheduled, must be considered with the total of licensed nursing home beds, plus the number of beds from approved certificates of need, but yet unlicensed.

(k) This part does not require a certificate of need for a home care organization that is authorized to provide only professional support services as defined in § 68-11-201.

(l) Except as provided in subsection (w), a home care organization may only initiate hospice services after applying for and receiving a certificate of need for providing hospice services.

(m)

(1) A person who provides magnetic resonance imaging services shall file with the agency an annual report no later than thirty (30) days following the end of each state fiscal year that details the mix of payers by percentage of cases for the prior calendar year for its patients, including private pay, private insurance, uncompensated care, charity care, medicare, and medicaid.

(2) In a county with a population in excess of one hundred seventy-five thousand (175,000), according to the 2010 federal census or a subsequent federal census, a person who initiates magnetic resonance imaging services shall notify the agency in writing that imaging services are being initiated and shall indicate whether magnetic resonance imaging services will be provided to a patient who is fourteen (14) years of age or younger on more than five (5) occasions per year.

(n)

(1) An application for certificate of need for organ transplantation must separately:

(A) Identify each organ to be transplanted under the application; and

(B) State, by organ, whether the organ transplantation recipients will be adult patients or pediatric patients.

(2) After an initial application for transplantation has been granted, the addition of a new organ to be transplanted or the addition of a new recipient category requires a separate certificate of need. The application must:

(A) Identify the organ to be transplanted under the application; and

(B) State whether the organ transplantation recipients will be adult patients or pediatric patients.

(3)

(A) For the purposes of certificate of need approval for organ transplantation programs under this part, a program submitted to the United Network for Organ Sharing (UNOS) by January 1, 2017, is not required to obtain a certificate of need.

(B) If the organ transplantation program ceases to be a UNOS-approved program, then a certificate of need is required.

(o)

(1) Within two (2) years after the date of receiving a certificate of need, an outpatient diagnostic center must become accredited by the American College of Radiology in the modalities provided by that facility as a condition of receiving the certificate of need.

(2) An outpatient diagnostic center that fails to comply with the accreditation requirement of subdivision (o)(1) is subject to licensure sanction under § 68-11-207 as a violation of part 2 of this chapter or of the rules, regulations, or minimum standards issued pursuant to part 2 of this chapter.

(p)

(1) Notwithstanding this title to the contrary, a certificate of need is not required for a hospital to operate a nonresidential substitution-based treatment

center for opiate addiction if the treatment center is located on the same campus as the operating hospital and the hospital is licensed under title 33 or this title.

(2) For purposes of this subsection (p), "campus" has the same meaning as defined in 42 CFR § 413.65.

(q)

(1) This part does not require a certificate of need for actions in a county that, as of January 1, 2021:

(A) Is designated as an economically distressed eligible county by the department of economic and community development pursuant to § 67-6-104, as updated annually; and

(B) Has no hospital that is actively licensed under this title located within the county.

(2)

(A) A person that provides positron emission tomography services or magnetic resonance imaging services pursuant to this subsection (q) must be accredited by The Joint Commission or the American College of Radiology in the modalities provided by that person and submit proof of the accreditation to the agency within two (2) years of the initiation of service.

(B) A person that provides positron emission tomography services or magnetic resonance imaging services pursuant to this subsection (q) and that fails to comply with the accreditation requirement of subdivision (q)(2)(A) is subject to licensure sanction under § 68-11-207 as a violation of part 2 of this chapter or of the rules, regulations, or minimum standards issued pursuant to part 2 of this chapter.

(r)

(1) This part does not require a certificate of need to establish a home health agency limited to providing home health services under the federal Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA) (42 U.S.C. § 7384, et seq.), or a subsequent amendment, revision, or modification to the EEOICPA. A license issued by the department pursuant to this subsection (r) for services under the EEOICPA must be limited to the provision of only those services. A home health agency providing home health services without a certificate of need pursuant to this subsection (r) must be accredited by The Joint Commission, the Community Health Accreditation Partner, or the Accreditation Commission for Health Care and submit proof of such accreditation to the agency within two (2) years of the initiation of service.

(2) A home health agency that provides home health services without a certificate of need pursuant to this subsection (r) and that fails to comply with the accreditation requirement of subdivision (r)(1) is subject to licensure sanction under § 68-11-207 as a violation of part 2 of this chapter or of the rules, regulations, or minimum standards issued pursuant to part 2 of this chapter.

(s)

(1) This part does not require a certificate of need to establish a home health agency limited to providing home health services to patients less than eighteen (18) years of age. A license issued by the department pursuant to this subsection (s) for the provision of home health services to patients under eighteen (18) years of age must be limited to the provision of only those services.

(2) The agency may permit a home health agency providing home health services to patients under eighteen (18) years of age to continue providing home health services to the patient until the patient reaches twenty-one (21) years of age if:

(A) The patient received home health services from the home health agency prior to the date the patient reached eighteen (18) years of age; and

(B) The home health services are provided under a TennCare program.

(3)

(A) A home health agency that provides home health services without a certificate of need pursuant to this subsection (s) must, within two (2) years of the initiation of service, be accredited by and submit proof to the agency of the accreditation from:

(1) An accrediting organization with deeming authority from the federal centers for medicare and medicaid services;

(2) The Joint Commission;

(3) The Community Health Accreditation Partner; or

(4) The Accreditation Commission for Health Care.

(B) A home health agency that provides home health services without a certificate of need pursuant to this subsection (s) and that fails to comply with the accreditation requirement of subdivision (s)(3)(A) is subject to licensure sanction under § 68-11-207 as a violation of part 2 of this chapter or of the rules, regulations, or minimum standards issued pursuant to part 2 of this chapter.

(t) This part does not require a certificate of need in order for an existing hospital licensed by the department of mental health and substance abuse services to become licensed by the department of health as a satellite of an affiliated general acute care hospital as provided by § 33-2-403(b)(8)(B).

(u)

(1) This part does not require a certificate of need to establish or operate the following in a county with a population in excess of one hundred seventy-five thousand (175,000), according to the 2010 federal census or a subsequent federal census:

(A) Initiation of magnetic resonance imaging services, or increasing the number of magnetic resonance imaging machines used, as long as magnetic resonance imaging services are not provided to a patient who is fourteen (14) years of age or younger on more than five (5) occasions per year; or

(B) Initiation of positron emission tomography.

(2)

(A) A provider of positron emission tomography established without a certificate of need pursuant to this subsection (u) must become accredited by the American College of Radiology and provide to the agency proof of the accreditation within two (2) years of the date of licensure.

(B) A provider of positron emission tomography established without a certificate of need pursuant to this subsection (u) and that fails to comply with the accreditation requirement of subdivision (u)(3)(A) is subject to licensure sanction under § 68-11-207 as a violation of part 2 of this chapter or of the rules, regulations, or minimum standards issued pursuant to part 2 of this chapter.

(v)

(1) A person who performs the following actions shall file an annual report as described in this subsection (v) with the health services and development agency:

(A) Cardiac catheterization;

(B) Open heart surgery;

(C) Organ transplantation;

(D) Operation of a burn unit;

(E) Operation of a neonatal intensive care unit;

(F) Provision of home health services; or

(G) Provision of hospice services.

(2) The annual report required by subdivision (v)(1) must be submitted in a manner and on forms prescribed by the agency, and must include utilization data according to source of payment and zip codes of patient origin.

(3) A person required to submit an annual report by this subsection (v) must submit the annual report for the period coinciding with the state fiscal year ending June 30, 2021, on or before September 30, 2021. The annual report for each subsequent fiscal year must be submitted to the agency no later than thirty (30) days following the end of each state fiscal year.

(4) The agency may impose a civil penalty not to exceed fifty dollars ($50.00) per day, for each day an annual report required by this subsection (v) is late.

(w)

(1) This part does not require a certificate of need to establish a home care organization or residential hospice limited to providing hospice services, as defined in § 68-11-201, to patients under the care of a healthcare research institution, as defined in § 68-11-1901.

(2) A license issued by the department pursuant to the exception created by subdivision (w)(1) must be limited to the provision of services only to the patients of the healthcare research institution, as defined in § 68-11-1901, or the patients of a hospital or clinic that has its principal place of business located in this state and that is affiliated with the healthcare research institution.

(3) A home care organization or residential hospice that provides hospice services without a certificate of need pursuant to subdivision (w)(1) must, within twelve (12) months of the date the home care organization is granted a license by the department, be accredited by The Joint Commission, the Community Health Accreditation Partner (CHAP), DNV GL Healthcare, or the Accreditation Commission for Health Care (ACHC), in order to continue to qualify for the exception created by subdivision (w)(1).

68-11-1608. Applications on consent or emergency calendars – Authority to grant emergency certificate of need.

(a) The executive director may place applications to be considered on a consent or emergency calendar established in accordance with agency rule.

(b) The rule must provide that, in order to qualify for the consent calendar, an application must not be opposed by a person with legal standing to oppose and the application must appear to be necessary to provide needed health care in the area to be served, provide health care that meets appropriate quality standards, and demonstrate that the effects attributed to competition or duplication would be positive for consumers. If opposition is stated in writing prior to the application being formally considered by the agency, then the application must be taken off the consent calendar and placed on the next regular agenda, unless waived by the parties.

(c)

(1) If an unforeseen event necessitates action of a type requiring a certificate of need, and the public health, safety, or welfare would be unavoidably jeopardized by compliance with the standard procedures for the application for and granting of a certificate of need, then the agency may issue an emergency certificate of need.

(2) An emergency certificate of need may be issued upon request of the applicant if the executive director and officers of the agency concur, after

consultation with the appropriate reviewing agency. Prior to an emergency certificate of need being granted, the applicant must publish notice of the application in a newspaper of general circulation, and agency members must be notified by agency staff of the request.

(3) A decision regarding whether to issue an emergency certificate of need must be considered at the next regularly scheduled agency meeting unless the applicant's request is necessitated by an event that has rendered its facility, equipment, or service inoperable. In that case, the agency's chair and vice chair may act immediately, on behalf of the agency, to consider the application for an emergency certificate of need.

(4) An emergency certificate of need is valid for a period not to exceed one hundred twenty (120) days. However, if the applicant has applied for a certificate of need under standard agency procedures, then an extension of the emergency certificate of need may be granted.

68-11-1609. Decision on application.

(a) The agency shall, upon consideration of an application and review of the evaluation and other relevant information:

(1) Approve part or all of the application and grant a certificate of need, upon lawful conditions that the agency deems appropriate and enforceable on the grounds that those parts of the proposal appear to meet applicable criteria. However:

(A) A condition that is placed on a certificate of need, and that appears on the face of the certificate of need when issued, must also be made a condition of any corresponding license issued by the department of health or department of mental health and substance abuse services. Notwithstanding a law to the contrary, the condition survives the expiration of the certificate of need and remains effective until removed or

modified by the agency. The condition becomes a requirement of licensure and must be enforced by the respective licensing entity; and

(B) The holder of a license or certificate of need that has a condition placed on it by the agency may subsequently request that the condition be removed or modified, for good cause shown. The agency shall consider the request and determine whether or not to remove or modify the condition. The procedure for requesting a determination must be done as provided by agency rules. If the holder of the license or certificate of need is aggrieved by the agency's decision, then the holder may request a contested case hearing as permitted by this part;

(2) Disapprove part or all of the application and deny a certificate of need on the grounds that the applicant has not affirmatively demonstrated that those parts of the proposal meet the applicable criteria; or

(3) Defer making a decision for no more than ninety (90) days to obtain a clarification of information concerning applications properly before the agency, if there are no simultaneous review applications being concurrently considered by the agency with the deferred application.

(b) A certificate of need shall not be granted unless the action proposed in the application is necessary to provide needed health care in the area to be served, will provide health care that meets appropriate quality standards, and the effects attributed to competition or duplication would be positive for consumers. In making these determinations, the agency shall use as guidelines the goals, objectives, criteria, and standards adopted to guide the agency in issuing certificates of need. Until the agency adopts its own criteria and standards by rule, those in the state health plan apply. Additional criteria for review of applications must also be prescribed by the rules of the agency.

(c) Activity authorized by a certificate of need must be completed within a period not to exceed three (3) years for hospital and nursing home projects, and two (2) years for all other projects, from the date of its issuance and after such time the certificate of need authorization expires. However, the agency may, in granting the certificate of need, allow longer periods of validity for certificates of need for good cause shown. Subsequent to granting the certificate of need, the agency may extend a certificate of need for a period upon application and good cause shown, accompanied by a nonrefundable reasonable filing fee, as prescribed by rule. A certificate of need authorization that has been extended expires at the end of the extended time period. The decision whether to grant an extension is within the sole discretion of the agency and is not subject to review, reconsideration, or appeal.

(d) If the time period authorized by a certificate of need has expired, then the certificate of need authorization is void. A revocation proceeding is not required. A license or occupancy approval shall not be issued by the department of health or the department of mental health and substance abuse services for an activity for which a certificate of need has become void.

(e) The agency's decision to approve or deny an application is final and shall not be reconsidered after the adjournment of the meeting in which the matter was considered. This subsection (e) does not limit the right to file a petition for a contested case hearing pursuant to § 68-11-1610, nor does it limit the Uniform Administrative Procedures Act, compiled in title 4, chapter 5, pertaining to contested case hearings.

(f) Written notice of the agency decision approving, disapproving, or deferring an application, or parts of an application, must be transmitted to the applicant, simultaneous review applicants, the department of health, the department of mental health and substance abuse services, the department of intellectual and developmental disabilities, and others upon request.

(g)

(1) A healthcare institution wishing to oppose a certificate of need application must be located within a thirty-five-mile radius of the location of the action proposed. A healthcare institution wishing to oppose an application for the establishment of a home care organization, the modification of a certificate of need issued to a home care organization, or the addition of counties to the licensed service area of an existing home care organization must have served patients in at least one (1) of the counties in the application's proposed service area within the seven hundred thirty (730) days immediately preceding the filing date of the certificate of need application, rather than demonstrate proximity within a thirty-five-mile radius of the location.

(2) Subject to subdivision (g)(1), a healthcare institution wishing to oppose a certificate of need application must file a written objection with the agency specifying reasons why one (1) or more of the criteria of subsection (b) are not satisfied. A healthcare institution wishing to oppose a certificate of need application must serve a copy to the contact person for the applicant, not later than fifteen (15) days before the agency meeting at which the application is originally scheduled. An application for which the agency has received opposition must be designated on the agency's agenda as an opposed application.

(3)

(A) Subject to subdivision (g)(1), a healthcare institution wishing to oppose a certificate of need application may appear before the agency and express opposition to the application as long as the healthcare institution has submitted written opposition in accordance with subdivision (g)(2).

(B) This subsection (g) does not prohibit an individual acting in the individual's capacity as a private citizen from appearing before the agency and expressing opposition to an application.

(4) A healthcare institution or other person expressing opposition to an application does not have a veto over an application. The merits of opposition may be considered by the agency while determining whether to approve or deny a certificate of need application in whole or in part.

(h) The agency shall maintain continuing oversight over a certificate of need that it approves on or after July 1, 2016. Oversight by the agency includes requiring annual reports concerning appropriate quality measures as determined by the agency. The agency may impose conditions on a certificate of need that require the demonstration of compliance with quality measures as long as the conditions for quality measures are not more stringent than those measures identified by the applicant in the applicant's submitted application.

(i)

(1) Notwithstanding a law to the contrary, and except as provided in subdivision (i)(2), a certificate of need and activity the certificate authorizes becomes void if the actions the certificate authorizes have not been performed for a continuous period of one (1) year after the date the certificate of need is implemented. With respect to a home care organization, this subsection (i) applies to each county for which the home care organization is licensed. A revocation proceeding is not required. The department of health and the department of mental health and substance abuse services shall not issue or renew a license for an activity for which certificate of need authorization has become void.

(2)

(A) The agency may issue a temporary exemption to subdivision (i)(1) upon finding that sufficient cause for the temporary cessation of the activity has been presented to the agency along with a plan to resume the activity in the future.

(B) The agency shall prescribe the procedures for issuing temporary exemptions by rule.

(C) The agency's approval or denial of a temporary exemption is a final agency decision subject to appeal in the chancery court of Davidson County.

(3) This subsection (i) does not apply to the establishment of a healthcare institution or a healthcare institution's number of licensed beds if the healthcare institution has a license issued under this title, whether active or inactive.

(j) If an applicant's application is denied by the agency, then the agency shall provide to the applicant written documentation with an explanation of the factual and legal basis upon which the agency denied the certificate of need.

68-11-1610. Contested case hearings— Petition — Procedure — Arbitration and mediation alternatives — Orders — Costs.

(a) Within fifteen (15) days of the approval or denial by the agency of an application, an applicant, a healthcare institution that satisfied the requirements set forth in § 68-11-1609(g), or another person who objected to the application pursuant to § 68-11-1609(g)(2) or (g)(3), may petition the agency in writing for a hearing. The petition must be filed with the executive director. Notwithstanding another law, all persons are barred from filing a petition for a contested case hearing after the fifteen-day period, and the agency has no jurisdiction to consider a late-filed petition. Upon receipt of a timely filed petition, the agency shall initiate a contested case proceeding as provided in this section. At the hearing, no issue may be raised or evidence considered concerning the

merits of an applicant considered by simultaneous review, unless the applicant met the requirements of this part, of concurrent consideration with the application that is the subject of the hearing.

(b) The contested case hearing required by this section must be conducted in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5, except as otherwise provided in this section.

(c) Contested cases initiated pursuant to this section must be heard by an administrative law judge sitting alone. Petitions for contested cases received by the agency must be forwarded immediately to the administrative division of the secretary of state's office for assignment to an administrative law judge.

(d) The administrative law judge to whom a case has been assigned shall convene the parties for a scheduling conference within fifteen (15) days of the date the petition for contested case is filed. At the scheduling conference, the parties shall state their respective positions on the mediation alternative described in this section. If the parties are unable to agree on a mediation alternative, then the scheduling order for the contested case adopted by the administrative law judge must establish a schedule that results in a hearing completed within one hundred eighty (180) days of the date on which the petition for contested case was received by the agency, with the initial order to be entered within sixty (60) days of the date the hearing is completed. Extensions of time or variances from the scheduling order must be granted sparingly, and only because of unforeseen developments that would cause substantial prejudice to a party.

(e) As an alternative to the contested case process described in subsection (c), the parties may agree to mediation of the issues raised in the contested case. The mediator shall be designated by mutual agreement of the parties. The parties may designate a mediator who is not listed as a qualified Supreme Court Rule 31 mediator, but such mediator shall observe the standards of professional conduct set forth in Appendix A to Supreme Court Rule 31, to the extent applicable. The mediator's fee

must be shared equally among the parties, except that the state is not required to contribute to payment of the mediator's fee. If mediation results in agreement of the parties, then the agreement must be memorialized in the order terminating the contested case. A mediation proceeding under this subsection (e) is not subject to the scheduling order requirements set forth in subsection (d).

(f) The general assembly declares the public policy of this state to be that certificate of need contested cases should be resolved through mediation, and the parties to such proceedings are encouraged to pursue this alternative.

(g) Judicial review of the agency's final order in a contested case is as provided by law.

(h) Costs of the contested case proceeding and appeals, including the administrative law judge's costs and deposition costs, such as expert witness fees and reasonable attorney's fees, must be assessed against the losing party in the contested case. If there is more than one (1) losing party, then the costs must be divided equally among the losing parties. Costs shall not be assessed against the agency.

(i) This section governs all contested cases relative to approval or denial decisions by the agency.

(j) If a person, who is not the applicant or the agency, seeks review of a decision in a contested case, then that person shall file an appeal fee equal to twenty-five percent (25%) of the examination fee for the application that was filed in the case.

68-11-1611. Review of progress — Revocation of certificate.

The agency shall, at least annually, review progress on a project covered by an issued certificate of need, and may require a showing by the holder of the certificate of substantial and timely progress to implement the project. If, in the opinion of the executive director, progress is lacking, then the executive director may present a petition for revocation of the certificate of need for the agency's consideration. The agency may

revoke the certificate of need based upon a finding that the holder has not proceeded to implement the project in a timely manner.

68-11-1612. Enjoining violations — Jurisdiction.

(a) The agency, in addition to the powers and duties expressly granted by this part, is authorized and empowered to petition a circuit or chancery court having jurisdiction to enjoin a person who is performing any of the actions specified in this part without possessing a valid certificate of need.

(b) Jurisdiction is conferred upon the circuit and the chancery courts of this state to hear and determine such causes as chancery causes, and to exercise full and complete jurisdiction in such injunctive proceedings.

68-11-1613. Appropriation/expenditures impact statement.

The division of TennCare or its successor, by the fifteenth of each month, shall submit to the chairs of the finance, ways and means committees of the senate and the house of representatives and to the office of legislative budget analysis a statement reflecting the estimated impact on future state appropriations or expenditures of applications approved by the agency the preceding month.

68-11-1614. Information submitted to agency by commissioners of health, mental health and substance abuse services, and intellectual and developmental disabilities.

(a) The commissioner of health shall provide the agency with aggregate data from the hospital discharge database and ambulatory surgical treatment center discharge database within seven (7) business days from the commissioner's receipt of a request. The information must include aggregate data by state, county, or zip code, as requested. The information must not include patient identifiers that would lead to a patient's identity, such as name or street address. Information received pursuant to this section must be available for public disclosure by the agency, as long as it does not contain patient identifiers.

(b) The commissioner of mental health and substance abuse services shall provide the agency with aggregate data about nonresidential substitution-based treatment centers for opiate addiction licensed in this state within seven (7) business days from the commissioner's receipt of a request. The information must include aggregate data about patient origin by state, county, or zip code, as requested, at licensee treatment centers in this state. The information must not include patient identifiers that would lead to a patient's identity, such as name or street address. Information received pursuant to this section must be available for public disclosure by the agency, as long as it does not contain patient identifiers.

(c) The commissioners of health, mental health and substance abuse services, and intellectual and developmental disabilities may submit written reports or statements and they may also send representatives to testify before the agency to inform the agency with respect to applications.

68-11-1615. Independent review and verification of information for joint annual report.

The commissioners of health, mental health and substance abuse services, and intellectual and developmental disabilities shall establish policies and procedures to ensure independent review and verification of information submitted by healthcare providers for inclusion in the joint annual report.

68-11-1616. Violations — Penalties.

(a) The agency has the power and authority, after notice and an opportunity for a hearing, to impose a civil monetary penalty against a person who performs, offers to perform, or holds such person out as performing an activity for which a certificate of need is required, without first obtaining a valid certificate of need.

(b) The executive director shall initiate a civil penalty proceeding by filing a petition with the agency. The proceeding must be conducted as a contested case

hearing in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5, part 3.

(c) The civil penalty is in an amount not less than one hundred dollars ($100) nor more than five hundred dollars ($500) per day of continued activity or operation. Once a civil penalty has been imposed, the violator has the burden of submitting verifiable evidence satisfactory to the agency that the violator has discontinued the activity for which the civil penalty was imposed. The penalty begins to accrue on the date the agency notified the violator of the violation or violations, and continues to accrue until such evidence of discontinuance is received at the agency office.

(d) An appeal of a final order imposing a civil penalty must be conducted in accordance with the Uniform Administrative Procedures Act.

(e) In determining whether to impose a civil penalty and the amount of the penalty, the agency may consider the following factors:

(1) The economic benefits gained from the activities in question. The agency does not have to show that the violator would not have been granted a certificate of need had one been sought;

(2) Whether the civil penalty and the amount of the penalty will be a substantial economic deterrent to the violator and others;

(3) The circumstances leading to the violation, and whether the violator had notice that the activity was in violation of the certificate of need laws or agency regulations;

(4) The financial resources of the violator, and the violator's ability to pay the penalty; and

(5) The failure to meet a quality standard applicable to the violator.

68-11-1617. Revocation of certificate of need — Grounds.

In addition to other grounds for revocation provided by other statutes, rule of law, or equity, the agency has the power to revoke a certificate of need whenever the following has occurred:

(1) The holder of a certificate of need has not made substantial and timely progress toward the completion of the project or acquisition of the equipment;

(2) The acquisition or project as described in the person's application has been changed or altered in a manner that significantly deviates from the acquisition or project approved by the agency when the certificate of need was granted;

(3) The decision to issue a certificate of need was based, in whole or in part, on information or data in the application which was false, incorrect, or misleading, whether intentional or not;

(4) The holder of the certificate of need has committed fraud in obtaining the certificate of need or has committed fraud upon the agency after the certificate of need was issued. For purposes of this section, "fraud" means a form of deceit, trickery, misrepresentation, or subterfuge, including, but not limited to, the following actions:

(A) Making a knowingly false statement, orally or in writing, in connection with a certificate of need application or project subject to the jurisdiction of the agency;

(B) Intentionally withholding or suppressing information that the person knows, or reasonably should know, is relevant to a certificate of need application or project subject to the jurisdiction of the agency; or

(C) Altering, forging, or otherwise modifying, with fraudulent intent, a document submitted to the agency in connection with a

certificate of need application or project subject to the jurisdiction of the agency; or

(5) The violation of a condition placed upon a certificate of need by the agency, prior to licensure by the department of health or department of mental health and substance abuse services.

68-11-1618. Nontransferability of certificate of need.

(a) Except as provided in this section, the transfer of a certificate of need renders the certificate of need and all rights under it void. As used in this section, "transfer" means the sale, assignment, lease, conveyance, purchase, grant, donation, gift, or other direct or indirect transfer of any nature whatsoever of a certificate of need. However, this section does not prohibit the transfer of a certificate of need in the following circumstances:

(1) If the transfer has been approved by the agency after the agency determines that the new holder of the certificate of need would provide health care that meets appropriate quality standards, and that the transfer would not reduce access to consumers, particularly those in underserved communities; those who are uninsured or underinsured; women and racial and ethnic minorities; TennCare or medicaid recipients; and low-income groups; and

(2) If the certificate of need is transferred as part of the transfer of ownership of a licensed healthcare institution.

(b)

(1) With regard to a certificate of need for the establishment of a proposed new healthcare institution, a change of control of the entity prior to completion or licensing renders the certificate of need and all rights under it null and void. "Change of control" means:

(A) In the case of a partnership, the termination of interest of a general partner;

(B) In the case of a limited liability company or limited liability partnership, a change in the composition of members or partners to the extent that the management or membership control is different than that described in the certificate of need application; and

(C) In the case of a corporation, the termination of interest of a shareholder or shareholders controlling more than fifty percent (50%) of the outstanding voting stock of the corporation.

(2) Subdivision (b)(1) does not prohibit change of control as described in subdivision (b)(1), if the agency determines, upon petition of the prospective owner or owners of the entity, that the prospective owner or owners demonstrate that they meet the criteria of economic feasibility, contribution of orderly development, and the considerations of § 68-11-1605.

(c) A certificate of need, and the rights under the certificate of need, are null and void if it is the subject of a development contract or agreement to sell or lease the facility that was not fully disclosed in the application.

68-11-1619. Application for medicare skilled nursing facility (SNF) beds.

(a) During each fiscal year after June 30, 2020, until June 30, 2025, the agency shall not issue certificates of need for new nursing home beds, including the conversion of hospital beds to nursing home beds or swing beds, other than one hundred twenty-five (125) beds per fiscal year, to be certified as medicare skilled nursing facility (SNF) beds as authorized in this section.

(b) The number of medicare SNF beds issued under this section shall not exceed thirty (30) for each applicant. The applicant shall specify in the application the skilled services to be provided and how the applicant intends to provide the skilled services. In reviewing applications, the agency shall consider the application without regard as to whether the applicant currently has medicare SNF beds. If the pool of one hundred twenty-five (125) medicare SNF beds created by this section is not depleted

prior to June 30 of the fiscal year, then the beds remaining in the pool must be considered to be available to applicants who apply before June 30 of each fiscal year, even though review may occur after June 30 of that year.

68-11-1620. Account for disposition of fees — Budget.

(a) Fees and civil penalties authorized by this part must be paid by the health services and development agency or the collecting agency to the state treasurer and deposited in the state general fund and credited to a separate account for the agency. Fees include, but are not limited to, fees for the application of certificates of need, subscriptions, project cost overruns, copying, and contested cases. Disbursements from that account may only be made for the purpose of defraying expenses incurred in the implementation and enforcement of this part by the agency. Funds remaining in the account at the end of a fiscal year do not revert to the general fund but remain available for expenditure in accordance with law.

(b) The agency shall prescribe fees by rule as authorized by this part. The fees must be in an amount that, in addition to the fees prescribed in subsection (c), provides for the cost of administering the implementation and enforcement of this part by the agency. The agency shall adjust the prescribed fees as necessary to provide that the account is fiscally self-sufficient and that revenues from fees do not exceed necessary and required expenditures.

(c) The agency shall annually collect the following schedule of fees from healthcare providers, and the fees must be paid to the state treasurer and deposited in the state general fund and credited to the agency's separate account. The following schedule applies:

(1) Residential hospice ..... $100 per license;

(2) Nursing homes 1-50 beds ..... $500 per license;

(3) Nursing homes 51-100 beds ..... $1,500 per license;

(4) Nursing homes 101+ beds ..... $2,500 per license;

(5) Hospitals 1-100 beds ..... $2,000 per license;

(6) Hospitals 101-200 beds ..... $3,500 per license;

(7) Hospitals 201+ beds ..... $5,000 per license;

(8) Ambulatory surgical treatment centers ..... $2,000 per license;

(9) Outpatient diagnostic centers ..... $2,000 per license;

(10) Home care organizations authorized to provide home health services or hospice services ……..... $500 per license;

(11) Birthing Centers..... $50 per license;

(12) Nonresidential substitution-based treatment centers for opiate addiction ..... $500 per license;

(13) Mental health residential treatment facilities..... $100 per license;

(14) Intellectual disability institutional habilitation facilities ..... $100 per license.

68-11-1621. Participation by local governing body in hearing for certificate of need application.

At a hearing conducted by the agency for a certificate of need application, if a local governing body requests to participate in the hearing, then the officials of the local governing body may appear before the agency and express support or opposition to the granting of a certificate of need to the applicant. The testimony of such officials is informational and advisory to the agency, and the support of the local governing body is not a requirement for the granting of a certificate of need by the agency.

68-11-1622. State health planning division of the department of health.

(a) There is created the state health planning division of the department of health. It is the purpose of the planning division to create a state health plan that is evaluated and updated at least annually. The plan guides the state in the development of healthcare programs and policies and in the allocation of healthcare resources in this state.

(b) It is the policy of this state that:

(1) Every citizen should have reasonable access to emergency and primary care;

(2) The state's healthcare resources should be developed to address the needs of Tennesseans while encouraging competitive markets, economic efficiencies, and the continued development of the state's healthcare industry;

(3) Every citizen should have confidence that the quality of health care is continually monitored and standards are adhered to by healthcare providers; and

(4) The state should support the recruitment and retention of a sufficient and quality healthcare workforce.

(c) The planning division is administratively staffed by the department of health in a manner that the department deems necessary for the performance of the planning division's duties and responsibilities, which may include contracting for the services provided by the division through a private person or entity.

(d) The duties and responsibilities of the planning division include:

(1) To develop and adopt a state health plan, which must include, at a minimum, guidance regarding allocation of this state's healthcare resources;

(2) To submit the state health plan to the governor for approval and adoption;

(3) To hold public hearings as needed;

(4) To review and evaluate the plan at least annually;

(5) To respond to requests for comment and recommendations for healthcare policies and programs;

(6) To conduct an ongoing evaluation of this state's resources for accessibility, including, but not limited to, financial, geographic, cultural, and quality of care;

(7) To review the health status of Tennesseans as presented annually to the planning division by the department of health, the department of mental health and substance abuse services, and the department of intellectual and developmental disabilities;

(8) To review and comment on federal laws and regulations that influence the healthcare industry and the healthcare needs of Tennesseans;

(9) To involve and coordinate functions with state entities as necessary to ensure the coordination of state health policies and programs in this state;

(10) To prepare an annual report for the general assembly and recommend legislation for their consideration and study; and

(11) To establish a process for timely modification of the state health plan in response to changes in technology, reimbursement, and other developments that affect the delivery of health care.

68-11-1623. Replacement facility applications — Certificates of need for nursing home beds.

(a) A replacement facility application is an application that proposes to replace one (1) or more currently licensed nursing homes with one (1) single licensed nursing home.

(b) An application or portion of a replacement facility application that does not increase the number of licensed beds over the number of beds in the existing facility or facilities being replaced must be reviewed by the department and considered by the agency pursuant to the criteria in § 68-11-1609(b), and shall not be considered new nursing home beds. In reviewing the application, the agency shall give preference to projects that propose replacement facilities because of building or life safety standard issues. The criteria of § 68-11-1619 do not apply to replacement facility applications.

(c) If a replacement facility application seeks to increase the number of licensed beds over the number of beds in the existing facility or facilities being replaced, then that

portion of the application that increases the number of beds must comply with § 68-11-1619, and is considered new nursing home beds. The remaining part of the application relative to the replacement of the facility or facilities must be reviewed by the department and considered under the criteria set out in subsection (b). In reviewing such an application, the agency shall give preference to projects that propose replacement facilities because of building or life safety standard issues.

(d) With regard to a certificate of need to replace a nursing home that has ceased operations, the original facility is not required to maintain its license after the certificate of need has been approved for the replacement facility.

68-11-1624. Delegation of authority to the department to issue new license to successor owner.

With regard to a healthcare facility that has been the subject of a change of control as defined by regulation, the board for licensing health care facilities in its discretion may delegate to the department the authority to issue a new license to the successor owner. The delegation of this authority is limited to circumstances where:

(1) The successor owner meets the qualifications for a license;

(2) The healthcare facility has no outstanding license or certification deficiencies; and

(3) The successor owner already owns or controls at least one (1) other healthcare facility in this state.

68-11-1625. Development of measures for assessing quality of entities receiving certificate of need — Failure to meet quality measures — Penalties.

(a) In consultation with the department of health, the department of mental health and substance abuse services, and the department of intellectual and developmental disabilities, and subject to § 68-11-1609(h), the agency shall develop by rule measures for assessing quality for entities that, on or after July 1, 2016, receive a certificate of need under this part. In developing quality measures, the agency may seek

the advice of stakeholders with respect to certificates of need for specific institutions or services.

(b) If the agency determines that an entity has failed to meet the quality measures developed under this section, then the agency shall refer that finding to the board for licensing health care facilities or the department of mental health and substance abuse services, whichever is appropriate, for appropriate action on the license of the entity under part 2 of this chapter.

(c) If the agency determines that an entity has failed to meet a quality measure imposed as a condition for a certificate of need by the agency, then the agency may impose penalties pursuant to § 68-11-1616 or revoke a certificate of need pursuant to § 68-11-1617.

68-11-1626. Renewal of license for closed hospitals in rural or distressed counties.

(a) Notwithstanding this part, a certificate of need is not required for the establishment of a hospital licensed under this title if:

(1) The hospital was previously licensed under this title or another hospital was previously licensed under this title at the proposed location;

(2) The hospital is located in a county:

(A) Designated by the department of economic and community development as a tier 2, tier 3, or tier 4 enhancement county pursuant to § 67-4-2109; or

(B) With a population less than forty-nine thousand (49,000), according to the 2010 federal census or a subsequent census;

(3) The last date of operations at the hospital, the hospital site service area, or proposed hospital site service area was no more than fifteen (15) years prior to the date on which the party seeking to establish the hospital submits information to the department pursuant to subsection (b); and

(4) The party seeking to establish the hospital applies for a certificate of need from the agency within twelve (12) months of the date on which the party submits information to the department pursuant to subsection (b).

(b)

(1) Notwithstanding this part, the department may renew a license for a hospital meeting the criteria in subdivisions (a)(1)-(3) upon application by the party seeking to establish the hospital and finding that the hospital will operate in a manner that is substantially similar to the manner authorized under the previous hospital's license at the time of the previous hospital's closure.

(2) The department shall review and make a determination on an application submitted pursuant to subdivision (b)(1) and notify the applicant in writing of the determination within sixty (60) days of the date the applicant submits a completed application to the department. If the department determination is to deny the application, then the department must also provide to the applicant a written explanation detailing the reasons for the denial.

SECTION 2. Tennessee Code Annotated, Section 4-29-242(a)(28), is amended by deleting the subdivision.

SECTION 3. Tennessee Code Annotated, Section 4-29-244(a)(1), is amended by deleting the subdivision.

SECTION 4. Tennessee Code Annotated, Section 4-29-245(a), is amended by adding the following as new subdivisions:

( ) Board for licensing health care facilities, created by § 68-11-203;

( ) Health services and development agency, created by § 68-11-1604;

SECTION 5. The headings to sections in this act are for reference purposes only and do not constitute a part of the law enacted by this act. However, the Tennessee Code Commission is requested to include the headings in any compilation or publication containing this act.

SECTION 6. For the purpose of rulemaking, this act takes effect upon becoming a law, the public welfare requiring it. For all other purposes, this act takes effect October 1, 2021, the public welfare requiring it.